UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

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KATHLEEN ROUSE individually and as Personal Representative of the estate of her deceased husband, WILLIAM PERRY ROUSE, 08 CV 00235

Plaintiff,

against-

SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,

Defendants.

COMPLAINT



Plaintiff, by attorneys, MORELLI RATNER PC and BALKIN & EISBROUCH, LLC, as and for the Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by the Plaintiff, KATHLEEN ROUSE individually and as Personal Representative of the estate of her deceased husband, WILLIAM PERRY ROUSE, (hereinafter referred to as "Plaintiff"), as the direct and proximate result of the wrongful conduct of the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, (hereinafter referred to as "Defendants" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia (rosiglitazone).

- 2. Jurisdiction exists as against the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, pursuant to:
- 28 U.S.C. Section 1332, in that the Plaintiff, KATHLEEN ROUSE (a) individually and as Personal Representative of the estate of her deceased husband, WILLIAM PERRY ROUSE, is a citizen and resident of the State of New York, the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, are a Pennsylvania corporation with their principal place of business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania, and regularly conducts business in the State of New York, and the amount in controversy exceeds the sum of \$75,000.00 exclusive of interest and costs.
- 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity (b) of citizenship, and the Judicial District of the Southern District of New York is a Judicial District in which a substantial part of the events or omissions giving rise to the claim occurred.
- That at all times hereinafter mentioned, upon information and belief, Defendant, 3. SMITHKLINE BEECHAM CORPORATION, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.
- That at all times hereinafter mentioned, upon information and belief, Defendant, 4. SMITHKLINE BEECHAM CORPORATION, was and still is a foreign corporation authorized to do business in the State of New York.

- 5. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION, was and still is a business entity actually doing business in the State of New York.
- 6. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.
- 7. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of New York.
- 8. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a business entity actually doing business in the State of New York.
- 9. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.
- 10. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of New York.
- 11. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a business entity actually doing business in the State of New York.
- 13. That at all times hereinafter mentioned, upon information and belief, Defendants presently market and sell the drug Avandia.

- 14. That at all relevant dates herein mentioned, Defendants marketed and sold the drug Avandia.
- 15. That at all times hereinafter mentioned, upon information and belief, Defendants engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Avandia, and in pursuance of this business, transact business within the State of New York and contract to provide goods and services in the State of New York.
- 16. That at all times hereinafter mentioned, upon information and belief, Defendants committed a tortious act inside the State of New York, which caused injury to Plaintiff and Plaintiff's decedent inside the State of New York.
- 17. That at all times hereinafter mentioned, upon information and belief, Defendants committed a tortious act outside the State of New York, which caused injury to Plaintiff and Plaintiff's decedent inside the State of New York.
- 18. That at all times hereinafter mentioned, upon information and belief, Defendants regularly do and solicit business and engage in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.
- 19. That at all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect their acts to have consequences in the State of New York, and derive substantial revenue from interstate or international commerce.

BACKGROUND

STATEMENT OF THE CASE

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- 20. Type 2 diabetes is the most common form of diabetes, afflicting over18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are susceptible to heart problems, and many diabetics die of heart problems.
- 21. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet, as well as Avandaryl (hereinafter collectively referred to as "Avandia" unless otherwise specified). Only one other drug like it, pioglitazone, sold as Actos and Actoplus, made by Takeda Pharmaceuticals, is sold in the United States. In 2006, Advandia represented 37% of the U.S. market for oral diabetes treatments. Thus, there is a large U.S. market for such drugs, and Avandia faces only one competitor for that market.
- Avandia reportedly had total U.S. sales of \$2.2 billion in 2006, slightly less than the \$2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately thirteen million Avandia prescriptions were filled in the U.S. in 2006, with a one-month supply of Avandia selling for between \$90 and \$170. Avandia is critical to GSK's financial success, being the company's second largest selling drug after Advair (an asthma medication).
- 23. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis," and shared the preliminary results with the Food and Drug

Administration (FDA) in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

- 24. Not only was GSK aware of the dangers posed by Avandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.
- 25. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was impaired due to GSK's failure to warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.
- 26. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects. Instead, GSK concealed, suppressed and

failed to disclose these dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

27. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and continues to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.

* * *

Phase I trials typically involve health volunteers. These trials study the safety of the drug and its interaction with the body, for example, its concentration and duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.

Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues*.

If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required,* in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

http://www.gsk.com/research/clinical/index/html (emphasis supplied).

28. GSK has also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer." http://www.gsk.com/about/index.htm.

- 29. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.
- 30. Based on these representations, upon which Plaintiff and Plaintiff's decedent relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of ingesting Avandia, Plaintiff's decedent purchased and ingested Avandia believing that the drug would be safe and effective.
- 31. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.
- 32. To date, GSK has failed to warn or inform consumers, such as Plaintiff, Plaintiff's decedent, or Plaintiff's decedent's prescribing physician, of the known defects in Avandia that can lead to increased risks of cardiovascular events, including myocardial infarction, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiff and Plaintiff's decedent.
- 33. As a result of GSK's omissions and/or misrepresentations, Plaintiff's decedent ingested Avandia, suffered cardiovascular injury including a myocardial infarction, and died in or about January 2006 sustaining physical and financial damages including pain and suffering and death.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST DEFENDANTS FOR NEGLIGENCE

- 34. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 35. That at all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design, manufacture, testing, processing, marketing,

advertising, labeling, packaging, distribution, and sale of Avandia, and Defendants knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

- 36. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard for the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact was not reasonably safe for such use, and furthermore, Defendants failed to adequately warn of the increased risk of serious cardio-vascular events which Defendants knew or should have known about.
- 37. That Defendants were further negligent, reckless, grossly negligent, and wantonly and willfully displayed a morally culpable and conscious disregard for the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardio-vascular events and by failing to adequately warn the public of such risks.
- 38. The aforesaid incident and the injuries sustained by Plaintiff and Plaintiff's decedent were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff and Plaintiff's decedent, on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including Plaintiff, Plaintiff's decedent, and Plaintiff's decedent's prescribing physician, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

- 39. Defendants failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:
 - a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendants knew, or should have known, carried the risk of serious, life-threatening side effects:
 - b) Failure to adequately test the product prior to placing the drug Avandia on the market;
 - Failure to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;
 - d) Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;
 - e) Failure to advise consumers, such as plaintiff, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death.
 - f) Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.
 - g) Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and
 - h) Any and all other acts of negligence with respect to Avandia which may be shown up to and including the time of trial.
- 40. That at all times herein mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff and Plaintiff's decedent.

- 41. That at all times herein mentioned, Plaintiff's decedent did not contribute to Plaintiff's decedent's injuries by reason of any negligence or culpable conduct on Plaintiff's decedent's part.
- 42. That as a result of the aforesaid occurrence, and the injuries sustained by Plaintiff and Plaintiff's decedent resulting therefrom, Plaintiff and Plaintiff's decedent suffered extensive monetary and pecuniary losses, and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff's decedent was deprived of a chance for safe and effective and/or successful treatment.
- 43. By reason of the foregoing, Plaintiff and Plaintiff's decedent sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST DEFENDANTS FOR BREACH OF WARRANTY

- 44. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 45. That at all times hereinafter mentioned, upon information and belief, Defendants, by directly and indirectly advertising, marketing and promoting Avandia for the treatment of diabetes, and by placing this drug in the stream of commerce knowing that Avandia would be prescribed for the treatment of diabetes, in reliance upon the representations of Defendants, expressly warranted to all foreseeable users of this drug, including Plaintiff's decedent, that Avandia was safe and effective for the treatment of diabetes.

- 46. That Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Avandia to all foreseeable users, including Plaintiff's decedent, that Avandia was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for the treatment of diabetes, and that Avandia was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of diabetes.
- 47. That at all times hereinafter mentioned, Plaintiff and Plaintiff's decedent relied upon the aforesaid express and implied warranties by Defendants.
- 48. That at all times hereinafter mentioned, Plaintiff's decedent's use of Avandia prior to and at all times relevant herein, the above-described illnesses were consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Avandia, and Plaintiff's decedent's use of Avandia was reasonably contemplated, intended and foreseen by Defendants at the time of the distribution and sale of Avandia by Defendant, and, therefore, Plaintiff's decedent's use of Avandia was within the scope of the above-described express and implied warranties.
- 49. Defendants breached the aforesaid express and implied warranties because Avandia was not safe and effective for the treatment of diabetes, and because Plaintiff's decedent's use of Avandia for the treatment of diabetes, caused or contributed to the injuries described herein.
- 50. Plaintiff and Plaintiff's decedent gave appropriate notice to Defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.
- 51. By reason of the foregoing, Plaintiff and Plaintiff's decedent sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have

jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A THIRD CAUSE OF ACTION AGAINST DEFENDANTS FOR STRICT PRODUCTS LIABILITY

- 52. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 53. That at all times hereinafter mentioned, the drug Avandia was not suited for the treatment of diabetes, and was not safe and effective for the treatment of diabetes, even though Defendants directly and indirectly advertised, marketed and promoted Avandia for such use.
- 54. That at all times hereinafter mentioned, the drug Avandia was not safe and was not suited for the purposes for which Defendants, directly and indirectly, advertised, marketed and promoted the drug at the time Defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.
- 55. Avandia was defective and unreasonably dangerous when it left control of Defendants in one or more of the following manners:
 - a) The risk associated with use of Avandia far outweighed the utility derived from using the medication;
 - b) Defendants failed to provide adequate warnings regarding the hazards associated with the use of Avandia;
 - c) Defendants' product was defectively designed and unreasonably dangerous in design and composition in that other medications could achieve similar results without the risks presented by Avandia; and
 - d) Avandia failed to comply with express warrantees that the product was safe and effective for human consumption.
- 56. Defendants were in the business of designing, developing, manufacturing, rebranding, labeling, marketing, distributing and/or selling Avandia.

- 57. Defendants sold and/or distributed Avandia in a condition that posed unreasonable risks from reasonably anticipated use. Avandia was expected to and did reach Plaintiff's decedent without substantial change in condition from the time that it left the control of Defendants.
- 58. The defective conditions alleged herein rendered Avandia unreasonably dangerous to Plaintiff's decedent and proximately caused the injuries and damages for which this lawsuit seeks recovery.
- 59. The Avandia ingested by Plaintiff's decedent was defective and unreasonably dangerous when it left the control of Defendants.
- 60. The unreasonably dangerous characteristics of Avandia proximately caused the injuries and damages for which recovery is sought.
- 61. Defendants knew, or in the light of reasonably available knowledge, should have known, of the danger in Avandia that caused the damage for which recovery is sought. The ordinary user, consumer, or health care provider of Avandia would not and could not have realized such dangers.
- 62. Defendants neglected to provide Plaintiff and Plaintiff's decedent with warnings that reasonably could have been expected to catch the attention of a reasonably prudent person under similar circumstances taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product. Further, Defendants failed to provide warnings which could accurately advise and ordinary consumer of the scope, severity and likelihood of serious injury resulting from the use of its product. Had such warnings been provided, the injuries and damages sustained by Plaintiff and Plaintiff's decedent could have been avoided.

- 63. Defendants neglected to provide Plaintiff's decedent's prescribing physician with adequate warnings to accurately advise such physician of the increased severity and likelihood of serious injury resulting from the prescribing and ingestion of Avandia to patients such as Plaintiff's decedent.
- 64. Defendants' product failed to function as expected and there existed feasible design alternatives equally effective and useful that would have had a reasonable probability of preventing the harms sustained by Plaintiff and Plaintiff's decedent.
- 65. That at all times hereinafter mentioned, upon information and belief, Defendants assumed a strict products liability to users and to persons using Avandia, including Plaintiff's decedent, who sustained injuries, harm and damages by reason of the use of Avandia for purposes directly and indirectly advertised, marketed, and promoted by Defendants, including for the treatment of diabetes.
- 66. By reason of the foregoing, Plaintiff and Plaintiff's decedent sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST DEFENDANTS FOR FRAUDULENT MISREPRESENTATION

- 67. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 68. Defendants widely advertised and promoted Avandia as a safe and effective medication.
- 69. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff and Plaintiff's decedent. Additionally, by virtue of

Defendants' partial disclosures about the medication, in which Defendants touted Avandia as safe and effective treatment, Defendants had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff's decedent, to purchase Defendants' dangerous product.

- 70. Had Plaintiff and Plaintiff's decedent been aware of the hazards associated with Avandia, Plaintiff's decedent would not have consumed the product that lead proximately to Plaintiff's decedent's adverse health effects.
- 71. Defendants' advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff and Plaintiff's decedent, to purchase such product. Plaintiff and Plaintiff's decedent relied on these material misrepresentations in deciding to purchase and consume Avandia to Plaintiff's decedent's detriment.
- 72. The damages sustained by Plaintiff and Plaintiff's decedent were a direct and foreseeable result of, and were proximately caused by Defendants' misrepresentations, concealment and omissions.
- 73. Defendants' conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of Defendants' conduct, which was directed at Plaintiff and Plaintiff's decedent and the public generally, Defendants should also be held liable for punitive damages.

- Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff's decedent and other members of the public who were prescribed and ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of Defendants' conduct, and information and documents concerning the safety and efficacy of Avandia. Plaintiff may also rely on a tolling agreement with Defendants. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.
- 75. By reason of the foregoing, Plaintiff and Plaintiff's decedent sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST DEFENDANTS FOR VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW §§ 349 AND 350

- 76. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 77. Defendants acted, used and employed deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Avandia, for the treatment of diabetes to patients/consumers such as Plaintiff's decedent, and causing such patients/consumers to purchase, acquire and use Avandia for the treatment of diabetes, as prescribed by their physicians and medical providers.

in connection with the sale and advertisement of the drug Avandia, in violation of New York General Business Law §§ 349 and 350.

- 78. By reason of Defendants' acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff and Plaintiff's decedent, were caused to purchase and ingest Avandia, and thereby sustain serious personal injuries.
- 79. By reason of the facts and premises aforesaid, Plaintiff and Plaintiff's decedent were damaged in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter, costs and reasonable attorneys fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- (1) The sum of \$100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
- (2) The sum of \$100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
- (3) The sum of \$100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
- (4) The sum of \$100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and
- (5) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Fifth Cause of Action, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter, together with costs and reasonable attorneys fees.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all claims so triable in this action.

Dated: January ? , 2008.

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VICTORIA J. MANIATIS, ESQ.

BALKIN & EISBROUCH, LLC David Eisbrouch, Esq. 50 Main Street Hackensack, NJ 07061 Telephone: (201) 342-5545

TO: SMITHKLINE BEECHAM CORPORATION GLAXOSMITHKLINE and SMITHKLINE BEECHMAN CORPORATION d/b/a GLAXOSMITHKLINE 1 Franklin Plaza Philadelphia, PA 10516